

REMARKS

Claims 1-21 were examined. Figures 2 and 7 were objected to. Claims 1-21 were rejected under 35 USC §112, second paragraph. Claims 1-18 and 20 were rejected under 35 USC §102(b). Claims 19 and 21 were rejected under 35 USC 103(a). Claims 1, 3-6, 8 and 10 were rejected for obviousness-type double patenting in view of claims 1, 3-6 and 8 of parent application 10/634,297 (now US patent 6,950,028). Claims 2, 7, 9, 11-18 and 20 were rejected for obviousness-type double patenting in view of claims 1 and 9-15 of parent application 10/634,297 (now US patent 6,950,028). Claims 19 and 21 were rejected for obviousness-type double patenting in view of claim 15 of parent application 10/634,297 (now US patent 6,950,028) and in view of Soga and Nicholson.

Re-examination and reconsideration of the claims, as amended, is respectfully requested.

Response to section 1. Applicant acknowledges the length of the specification, which was required in order to both adequately review prior art, and disclose the new teaching in the context of prior art. Other than the drawing corrections, applicant is not currently aware of other errors, but will correct as they become apparent.

Response to section 2: drawing objections: Replacement drawing sheets for figures 2 and 7 are included in this response. Note that these corrected drawing sheets contain no new material, since the previously objected to "blank boxes" in Figures 2 and 7 were labeled with numbers, and the meaning of the numbers was clearly defined in the specification. For example Figure 2 "box 1" was previously defined in the specification as "microprocessor (1)" (present specification, paragraph 54), Figure 7 "box 1" was previously defined in the specification as "personal computer (1)" (present specification, paragraph 120), and so on. The replacement drawing sheets convey the same information in a more convenient form. These corrected figures are included at the end of this response.

Response to section 3.**Rejections under 35 USC §112, second paragraph**

To overcome this rejection, note that independent claims 1, 11, and 18 have now been amended in response to the specific 35 USC §112, second paragraph rejections, as well as the specific 35 USC §102(b) and 35 USC 103(a) rejections, discussed later in this document. As a result, all independent claims, and by reference, all dependent claims, now contain additional limitations that serve to further clarify and define the invention. These specific amendments are discussed in more detail in the following sections of this response.

Claims 1, 11 and 18 have been amended to replace the phrase "said computing means" to "said computational means".

Response to section 5.

Since all section 5 rejections were based on the prior art of Soga et. al. (US patent 5,867,809), applicant believes that before going into the detailed arguments, a brief overview of the art of Soga, and the present art, may be useful. Soga's art, and the present art, evolved in response to different types of problems, and each teaches different, but appropriate, ways to solve their different problems.

Brief review of Soga et al., and the art of the present disclosure

Soga was interested in recycling printed circuit boards from appliances that were returning from the field to the factory for warranty, repair, or scrap. The lifetime of printed circuit boards is largely determined by the probability that stress or fatigue, caused by extreme temperature cycling, will eventually cause a solder joint to fail. Thus boards from appliances subjected to heavy use in the field were statistically more likely to have highly stressed solder joints, and thus were poor candidates for reuse. Boards

from appliances subjected to light use in the field will have less stressed solder joints, and thus were more likely to be safely reused. Soga came up with the concept of embedding a temperature logger in the appliance's printed circuit boards. This logger recorded hours of appliance use each day, as well as the appliances' average temperature and temperature extremes (minimum and maximum). When the appliance was returned to the factory, the appliance was disassembled. Data from the temperature logger embedded in the printed circuit board was downloaded to a terminal at the factory. The factory terminal then analyzed the data using a solder joint fitness for use stress and strain function. The factory terminal stress and strain function took the hours of operation, and temperature extreme (minimum and maximum) data as an input, and computed fitness for use. The factory terminal then indicated to the factory workers if the printed circuit board could be reused or not.

By contrast, the present art evolved in response to a different set of problems. Medical materials (diagnostics, vaccines, pharmaceuticals, etc.) are often perishable products that fail due to temperature induced chemical deterioration, rather than by stress or strain. These materials are typically shipped by the manufacturer to thousands of different locations, such as the home, physician's offices, clinics, and hospitals. If these materials are subjected to undue temperature stress, which can easily happen during transport or storage, the material may be damaged, and severe consequences, including loss of life, are possible. In order to prevent problems, patients or physicians who are planning on using the material should ideally be able to glance at the material, and instantly know if the material is still good or not. Alternatively the material should continually report its status to an automated attendant. Thus the need for a small, unitized, device that can stay with the material, and immediately display fitness for use, should be apparent. Since prior art devices of this type had many limitations, the need to teach improvements in such devices should also be apparent, and is the focus of the present disclosure.

Thus, in broad scope, Soga taught a non-unitized (data collection and recording separate from data analysis) system where appliances in the field had printed circuit boards containing recorders that recorded hours of use and temperature extreme data. These

appliances were then later returned to the factory for repair, scrap, or rework. The factory removed the printed circuit boards, factory terminals downloaded the data, and these factory terminals then analyzed the data using "fitness for use" functions (for mechanical stress and strain) to predict the remaining lifetime of the printed circuit boards' multiple solder joints. By contrast, the present disclosure teaches an improved unitized device where the temperature data uptake means and the "fitness for use" means are present on the same device. The advantage of a unitized design is that "fitness for use" is continually displayed or output, allowing users to instantly know if a material is still good or not. The present disclosure also teaches improved fitness for use functions, capable of accurately handling complex chemical (i.e. non-mechanical stress or strain) time-temperature stability profiles. The present disclosure also teaches improved ways to rapidly customize these devices to a material with arbitrary stability characteristics.

Given this broad context, the specific rejections will now be examined in detail.

Rejections under 35 USC §102(b).

Response to section 5 - regarding claim 1. The rejection that Soga (US patent 5,867,809) in the abstract, column 12 lines 15-65; column 13 line 14 to column 14, line 55, and column 15, lines 1-25 anticipates the present invention under 35 USC §102(b), is respectfully traversed in part, and overcome in part.

Although it is stipulated that Soga's art, and the present art, are both combination hardware - software systems that monitor temperature, and produce fitness for use output, the two systems are otherwise quite different.

The 35 USC §102(b) rejection is respectfully overcome based on an amendment (limitation) to claim 1 (and other independent claims), which emphasizes some of the major differences between the hardware portion of the art of Soga, and the current disclosure.

The 35 USC §102(b) rejection is also respectfully traversed on based upon function and equation differences. Specifically, there are major differences between Soga's solder joint stress and strain "predetermined life equation", and the stability "function of temperature" taught by the present art.

Overcoming hardware issues

The 35 USC §102(b) rejection of claim 1 is respectfully overcome by adding a new limitation that specifically emphasizes one of the many hardware differences between the present art, and the art of Soga et. al.

In contrast to the present invention, Soga does not teach a unitized time-temperature indicating device, where both the temperature data uptake and subsequent data analysis and fitness for use output are done on the same device. Rather, Soga teaches a variation on traditional temperature logger - temperature analyzer methods in which the temperature recording function is present on one device, and the "fitness for use" or "stability" analysis is either done manually, or by using a second device that downloads data from the first device, and then processes the data.

In order to better compare the art of Soga and the present invention, the data collection and analysis aspects of the two inventions will be reviewed in more detail. Soga '809 teaches the utility of embedding time-temperature recording "IC with sensor" chips as sub components of printed circuit boards of electronic appliances. Soga's embedded time-temperature recording "IC with sensor" continually records the daily hours of operation, on-off cycles, and daily minimum, maximum, and average operating temperature throughout the lifetime of the electronic appliance (Soga Column 9 line 23 to Column 10, line 67). When the appliance is returned to the factory for repair, maintenance, or scrap, the printed circuit board is examined by an external terminal device (Soga figure 7) that is normally part of a factory disassembly line. This external terminal device downloads the daily operating data from the "IC with sensor". Note that

the downloaded data does not contain any explicit "fitness for use" flags or status information, but is rather a collection of raw daily, weekly or monthly operating time, minimum, maximum, and mean temperature, and on-off power cycles (See Soga Figure 4).

Soga's external terminal device then examines the data, using one or more mechanical stress and strain fitness for use algorithms. Note that Soga's fitness for use functions (algorithms) reside in the external terminal device (See Soga's Figure 7 item 8: and Soga Column 12 line 15 to Column 14 line 58), and that this external terminal device is required in order to determine if the printed circuit board is still fit for use or not. Users of the appliance in the field have no way of telling if the printed circuit board is still good, or not, because Soga's "IC with sensor" time-temperature recording chips do not contain onboard functions capable of rendering a "fitness for use" signal.

By contrast, the present invention teaches the utility of constructing unitized devices with both onboard time-temperature monitoring means, as well as onboard fitness for use stability function means, and onboard output means capable of allowing users in the field to make an instantaneous judgment as to fitness for use of the material or not. Note also that in contrast to Soga's art, which teaches only means to monitor the status of the appliances' own electronic printed circuit board (i.e. Soga's "IC with sensor" only monitors its own printed circuit board - see Soga Column 6, lines 42-47), the present invention teaches a more flexible and outward looking device designed to monitor the status of all materials, such as non-electronic perishable foods, medical supplies, organic materials, and the like.

Applicant respectfully submits that all of Soga's claims have some variation of a "*relation* [e.g. Soga's "predetermined life equation", or "fitness for use" function] *being obtained by external reading of the history of temperature*" limitation [emphasis added]. That is, Soga's "IC with sensor" device needs to be read by an external device in order to obtain meaningful results. This is in direct opposition to the "unitized" device, taught by all claims of the present disclosure, which teaches new art that does not require external

reading of the history of temperature. Thus Soga does not teach the present disclosure under 35 USC §102(b), but rather teaches against it.

Although the prior "unitized" limitation of Claim 1 was intended to teach that, in contrast to Soga and other methods of prior art, the temperature data acquisition means and the "fitness for use" function of temperature means both physically reside on the same device, this distinction may not have been totally clear. Applicant thus respectfully overcomes the 35 USC §102(b) rejection of claim 1 by amending claim 1 (as well as other independent claims 11 and 18) to further clarify this point. Claim 1 and all subsequent independent claims have been amended to further teach: and wherein said function of temperature resides with said unitized device. Since Soga's "predetermined life equation" (which Soga's uses to determine fitness for use) resides on a factory terminal device that is both physically different and separated from his "IC with sensor" temperature data acquisition device, applicant respectfully submits that this amendment overcomes the 35 USC §102(b) rejection of claim 1.

Traversing function and algorithm issues

Applicant also respectfully traverses the 35 USC §102(b) rejection of claim 1 on the grounds that the "function of temperature" taught by claim 1 (and all subsequent claims) of the present disclosure is not the same function as the "predetermined life equation" taught by Soga. Moreover, Soga's "predetermined life equation" is incapable of handling the stability of time-temperature sensitive materials described in the present specification, and thus is unsuited for the present art.

In contrast to the present disclosure, which gives specific instructions on how to construct a suitable "function of temperature" as a fundamental part of the claims, Soga gives no such detailed instructions. Instead, Soga's claims focus almost entirely on the hardware details of Soga's complex multi-component system, and for the "predetermined life equation" simply teach:

"calculated by a predetermined life equation of said component being indicated with a relation between the history of temperature and the history of operation status" (Soga Column 18, line 17-20. [Emphasis added] Note that variations of this limitation are in all of Soga's subsequent claims as well.

Soga's claims further define "operation status" as *"a use condition affecting the life of a component forming part of said printed circuit board"*. (Soga Column 14, line 66-67).

Applicant respectfully traverses the 35 USC §102(b) rejection of claim 1 on the basis that Soga's "predetermined life equation" does not teach the "function of temperature" taught in the present specification. Rather, Soga's "predetermined life equation" has both different types of input (e.g. Soga's input includes both "history of temperature", and "history of operation status"), and different types of output (probability of printed circuit board solder joint failures due to stress and strain) than the present stability function of temperature. For example, the present art does not incorporate *"a use condition affecting the life of a component forming part of said printed circuit board"* as part of its "function of temperature".

Since Soga was teaching monitoring the lifetime of the printed circuit board of an appliance that is electrically switched off and on many times over its operating life, Soga's teaching *"the history of operation status"*, limitation is appropriate for his printed circuit application, but not for the subject matter of the present invention. The present invention is primarily focused on monitoring the time-temperature stability lifetime of chemical materials that are not electrically switched on and off, and which may not be used at all while they are in storage. Thus, in contrast to Soga, the present "function of temperature", does not accept "operation status" as an input variable. Rather, the present disclosure's "function of temperature" monitors chemical materials that are usually external to the present devices' printed circuit board, and does not accept "operation status" variables such as "operation time" or "on - off number of time" (See Soga Figure 4) as input variables.

There are other differences between Soga's "predetermined life equation" and the present "function of temperature" as well. In order to expedite traversal of the 35 USC §102(b) rejections of claim 1 and other claims, specific subsections (i.e. clauses, limitations) of present claim 1 will be quoted and numbered for purposes of discussion, and then examined in detail. These limitations will then be contrasted with the teaching of Soga.

Contrast between present Claim 1's "function of temperature", and Soga's art:

Claim 1 of the present disclosure gives specific guidance on how to construct suitable fitness for use functions of temperature. Here, portions of claim 1 have been broken down into six numbered clauses, and each clause is analyzed separately. When this is done, it can be seen that claim 1 (and subsequent claims) teaches:

1: the device must compute a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device;

Here "operative" is used in the conventional sense, as defined in the Merriam-Webster dictionary as "*producing an appropriate effect*" or "*exerting force or influence*", and as defined in the Oxford English dictionary as "*functioning; having effect*". In this context, "continually operative" is intended to teach that the function of temperature continues to operate (i.e. return results) for all temperature values that the device monitors from the low end to the high end. This clause thus teaches that the function must return results for all intermediate values in between the low and high extremes.

Note that the clause 1 portion of claim 1, originally intended to further distinguish the present art from prior art temperature "alarm" functions which only give output at very low or very high temperatures (i. e. are not continually operative for intermediate temperatures), also distinguishes the present art from the teaching of Soga. As discussed in Soga Figure 4, and Soga column 9 line 32 to column 10, line 33, Soga's "IC with sensor" only records daily temperature minimum, maximum, and average values, and does not return any intermediate temperature values as input to the "predetermined life

equation" located on Soga's factory terminal device. Thus Soga's equation, being denied input from intermediate temperature values, obviously is not continually operative for these intermediate temperature values.

As an example, Soga cannot distinguish between 1: 12 hours at 0 °C followed by 12 hours at 30 °C; and 2: 1 hour at 0 °C, 10 hours at 10 °C, 10 hours at 20 °C, and 1 hour at 30 °C. Both cases produce the same daily maximum, minimum and average readings, but may produce very different "fitness for use" results with some materials. By contrast, the present art can distinguish between these two cases.

2: the function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material;

Soga teaches mechanical stress and strain functions for solder joints (Soga function 1, and function 2, column 7, line 21 to column 9, line 31). These functions are sensitive to daily fluctuations in temperature extremes (which can cause mechanical stress). They are insensitive to effects that non-fluctuating temperatures may have on the stability of chemical materials. As will be discussed in more detail in the analysis of Soga's figure 4 (see response to section 5, regarding claim 6), Soga's "IC with sensor" also fails to record the time-temperature data necessary to properly implement this function.

A more extensive discussion of the differences between this clause, and the art of Soga et. al., will be more extensively discussed in the traversal of the 35 USC §103(a) rejections of claims 6 and 15, discussed later in this document.

3: the computational emptying means generate a running sum of said function of temperature over time;

Soga fails to reveal any such running sum in his specification, and also fails to teach such running sum in his claims.

4: wherein said function of temperature resides with said unitized device; [current amendment]

As previously discussed, Soga's "predetermined life equation" does not reside with a unitized device, but rather in a separate factory terminal device.

5: the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material;

As previously discussed, Soga does not teach the importance of small granularity combined with frequent measurements. Rather, Soga teaches the reverse -- only measurement of temperature extremes (maximum, minimum, average) over long (daily) time intervals. Soga does not teach the importance of measuring temperature with small granularity (differences) between temperature values, or short intervals between time measurements.

A more extensive discussion of the differences between this clause, and the art of Soga et. al., will also be discussed in the traversal of the rejections of claims 6, 7 and 15.

6: the running sum is compared to a reference value, and the result of said comparison is used to generate an output signal indicative of the fitness for use of said material.

As previously discussed, Soga does not teach such running sums.

Thus the present rejection, that Soga anticipates the present art under 35 USC §102(b) is respectfully traversed and overcome on the grounds of multiple hardware and function differences between Soga, and the present art.

A continuation of this discussion of the differences between Soga's "predetermined life equation" and the present "function of temperature" can be found in the traversal of the rejections to claims 6, 7, 15, and 18, discussed later in this document.

Given this background, the specific sections of Soga, previously cited by the examiner (abstract, column 12 lines 15-65; column 13 line 14 to column 14, line 55, and column 15, lines 1-25), will now be reviewed in detail.

Review of Soga's abstract: Although Soga's abstract discloses *"a control unit controls storage of the history of temperature and humidity in correspondence with the history of operation status"*, nowhere in the abstract does Soga teach that the control unit for the "IC with sensor" (which is embedded in the appliances' printed circuit board), in fact calculates any sort of a "predetermined life equation" or "fitness for use". Rather Soga teaches only that the control unit controls the uptake and storage of data.

Soga teaches that this control unit: *"... allows, when the remaining life of the component is evaluated so as to decide whether or not to reuse it, external reading of the history of temperature and humidity corresponding to the history of operation status from the memory."* [Emphasis added]. Soga's abstract contains no suggestion that the "IC with sensor" makes any sort of independent fitness for use evaluations. Rather, the abstract only discusses "evaluation" in the context of "external reading".

Review of Soga, column 12 lines 15-65: Soga in column 12, lines 15-65, presents a detailed discussion of Soga's Figure 8. As noted in Soga's "Brief Description of the drawings", (column 6, lines 21-29):

Fig. 8 is a drawing showing a specific exemplary construction of the terminal device show in Fig. 7. [Emphasis added]

Fig. 7 is a drawing showing a system configuration for calculating the remaining life of each of the components and joints constituting an electric appliance collected by a

collection factory (disassembly factory) relating to the present invention, or a printed circuit board which is disassembled from the electric appliance and for deciding whether or not to reuse them. [Emphasis added]

Note that Soga's discussion of Fig. 8 in column 12, lines 15-65 is thus discussing the details of the "predetermined life equation" fitness for use equations that are performed by the external terminal device, which is located in Soga's factory. In other words, Soga's "IC with sensor" device on the printed circuit board simply collects time temperature data, and the outside factory "terminal device" does subsequent analysis. This configuration essentially replicates the traditional prior art for analysis of time-temperature loggers, as discussed in the specification for the present application. As the present specification discussed:

"The second type [of prior art] consists of non-indicating electronic time-temperature monitors, and electronic data loggers. This second type also monitors the time and temperature by chemical or electronic means, but does not output the [fitness for use] data in a manner that is readily accessible to unsophisticated users without additional equipment. Rather, this second class of electronic device requires specialized reading equipment, and may additionally require sophisticated data analysis on the part of the recipient of the material of interest." (present specification, paragraph 30). [Emphasis added]

Review of Soga, column 13 line 14 to column 14, line 55: This section of Soga discusses some further hardware and software details of the external terminal device that reads the data from the "IC with sensor" temperature logger located onboard Soga's printed circuit board. This section is a good example of the *"sophisticated data analysis on the part of the recipient of the material of interest"* cited by the present specification (paragraph 34) as exemplifying prior art. Note that without this sophisticated data analysis, Soga's "IC with sensor" cannot perform a fitness for use assessment. By contrast, the present disclosure teaches methods to enable fitness for use assessment without the need for an external terminal device, which is in marked contrast to the art of Soga et. al.

Review of Soga column 15, lines 1-25: This section is a detail of Soga's claim 1. Note that in claim 1, column 15, lines 15-23, Soga teaches:

"whereby said component can be evaluated for reuse by evaluating the remaining life thereof in accordance with a life of said component which is calculated by a predetermined life equation of said component being indicated with a relation between the history of temperature and the history of operation status, the relation being obtained by external reading of the history of temperature in correspondence with the history of operation status from said memory." [emphasis added]

Again, Soga is essentially teaching the prior art for temperature loggers, as previously discussed for the last section, where a prior art temperature logger:

"does not output the data in a manner that is readily accessible to unsophisticated users without additional equipment. Rather, this second class of electronic device requires specialized reading equipment, and may additionally require sophisticated data analysts on the part of the recipient of the material of interest". [present specification, paragraph 30] [Emphasis added].

Applicant thus respectfully submits that Soga is simply teaching another variation on prior art for temperature logging devices, in which data from the device must be read and subjected to sophisticated data analysis before any fitness for use decision can be made.

Response to section 5 - regarding claim 2

The rejection to claim 2 is respectfully traversed. Claim 2 is a dependent claim to claim 1, which, as previously discussed, was not anticipated by Soga. Additionally, applicant respectfully submits that Soga's "IC with sensor" temperature logger device does not contain any "predetermined life equation" or "fitness for use" means of any sort, and thus does not have a multi-element lookup table or equation parameters corresponding to claim 2.

Response to section 5, regarding claim 3

The rejection to claim 3 is respectfully traversed. Claim 3 is a dependent claim to claim 1, which, as previously discussed, was not anticipated by Soga. Additionally, applicant respectfully submits that Soga does not disclose a unitized device that outputs a visual signal or any other type of signal that is "indicative of the fitness for use of said material." Rather, Soga teaches a device where the fitness for use output resides on an external terminal device (See Soga Figure 8, item 84).

Soga's "IC with sensor" device only outputs "history data with respect to use condition and use environment" (Soga Figure 4), which requires additional analysis by Soga's "external terminal" device before a fitness for use signal can be generated.

To further clarify the differences between the "fitness for use" output signal for the present disclosure, and the raw "history data with respect to use condition and use environment" of Soga et. al., note the following example:

The present disclosure teaches a device that can function adequately by outputting only a binary "0" "1" type "good"/"bad" fitness for use signal, or a single number formed by the difference between the running sum and the reference value. This signal can thus be used to form a "fitness for use" assessment without any further processing or interpretation. By contrast, output from Soga's "IC with sensor" device requires a great deal of processing and manipulation before a "fitness for use" determination can be made. As a result, in order to function adequately, Soga's IC with sensor must by necessity output a vast amount of temperature history data, so that Soga's "external terminal device" can process this temperature history data using Soga's "predetermined life equation" stored on the "external terminal device", and make a final "fitness for use" assessment.

Response to section 5, regarding claim 4

This rejection is respectfully traversed in part, and overcome in part. Claim 4 is a dependent claim to claim 1, which as previously discussed was not anticipated by Soga.

Additionally, applicant respectfully traverses this rejection on the grounds that since, as previously discussed, Soga's teaches no unitized device, no equivalent function of temperature, and no unitized device memory allocated for the storage of "fitness for use" functions (e.g. "function of temperature, "predetermined life equation"), Soga clearly can not be teaching means to program such a non-existent (to Soga) device.

As previously discussed, Soga's "IC with sensor" device contains no memory allocated for a fitness for use "function of temperature", "predetermined life equation", or reference value of any sort. Soga is teaching a system where the function of temperature or predetermined life equation, used to compute fitness for use, resides on an external terminal device and not on the "IC with sensor" device. Thus in the abstract, column 12 lines 15-65; column 13 line 14 to column 14, line 55, and column 15, lines 1-25 Soga is teaching programming of an external terminal device, rather than the unitized temperature indicator device as taught in the claim 1 and 4 of the present application. Again, note that claim 1 has been amended to further clarify that: "said function of temperature resides with said unitized device."

These issues are discussed in further detail in the response to section 5, regarding claim 12 portion of this response.

Response to section 5, regarding claim 5

This rejection is respectfully traversed in part, and overcome in part. Claim 5 is a dependent claim to claim 1. As previously discussed, amended claim 1 was not anticipated by Soga. Soga fails to teach other key aspects of the present invention, such as a system in which the fitness for use function of temperature resides in the unitized

device. As previously discussed, independent claim 1 (as well as independent claims 11, and 18) has been amended to clarify this aspect of the present invention.

Applicant further respectfully traverses this rejection by noting that in Soga's Figure 4, Soga is clearly teaching "operation time" and "on-off number of time", which clearly teaches against the "continually powered throughout its use lifetime" limitation of claims 5 and 14.

Response to section 5, regarding claim 6

This rejection is respectfully traversed in part, and overcome in part. Claim 6 is a dependent claim to claim 1. Amended claim 1, as previously discussed, was not anticipated by Soga.

Applicant also respectfully traverses this rejection on additional grounds. Applicant agrees with the examiner's conclusion that Soga does not clearly disclose claim 6. In fact, as will be discussed, Soga teaches away from claim 6. Since Soga clearly is not teaching present claim 6 under 35 USC §102(b), and since examiner cites "obviousness" in this rejection, applicant assumes that the examiner intended to use a 35 USC §103(a) obviousness rejection rather than a 35 USC §102(b) prior-art objection. Thus applicant will respond to this rejection assuming that is a 35 USC §103(a) rejection.

Before responding specifically to this (assumed) 35 USC §103(a) rejection, applicant believes that a review of the obviousness criteria of MPEP 706.02(j) is in order:

MPEP 706.02(j): To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the

claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). See MPEP 2143 - 2143.03 for decisions pertinent to each of these criteria.

As discussed in MPEP 706.02(j) in order to establish obviousness, three basic criteria must be met. These are: 1: suggestion or motivation, 2: expectation of success, and 3: teaching of all claim limitations must be found in the prior art.

If Soga was, in fact, teaching a function of temperature similar to claim 6, this function would, at a minimum, need input data with "a temperature resolution granularity of 10 °C or smaller; and the periodicity of sampling has a time resolution granularity of 2 hours or smaller" in order to work. Thus Soga's "IC with sensor" device should at least be providing this type of data for submission to Soga's "predetermined life equation" onboard Soga's remote factory terminal device.

In fact, Soga's "IC with sensor" does not provide this type of data.

Note that in Soga's Figure 4, which teaches the "history data of the printed circuit board": Soga's embedded "IC with sensor" device only stores the temperature maximum, minimum, and mean for the day. No other intermediate temperature values are stored! This teaching of an "IC with sensor" that only records temperature maximum, minimum, and mean for the day is also found in the Soga's specification (Soga Column 2, lines 30-40; Column 2 lines 60-65; and Column 10, lines 5-21).

Why does Soga not record time and temperature data with more resolution (granularity)? This is due to the fact that Soga's "predetermined life equation" is quite different from the "function of temperature" taught in the present disclosure. Soga's specification (column 7, lines 20 to column 9, line 31) teaches solder joint life calculation formulas 1 and 2 (Soga column 7, lines 25-58), based on the Coffin Manson Equation for mechanical Fatigue. Mechanical fatigue is responsive to temperature extremes, and Soga's formulas

1 and 2, require only a maximum and minimum temperature in order to calculate a ΔT and T_{\max} value. As a result, Soga did not feel the need to teach obtaining and processing small granularity temperature values, as taught by the "temperature resolution granularity" language limitations of claim 6.

Applicant respectfully traverses the 35 USC §103(a), rejections of claim 6 based upon failure to meet the 1: "suggestion or motivation", criteria of MPEP 706.02(j). Specifically, Soga's "predetermined life equation" does not require temperature data with the granularity (resolution) taught by present claim 6. Rather Soga's "predetermined life equation" requires only average temperature, and temperature minimum and maximum data. Further, as previously discussed, Soga's "IC with sensor" does not present data within the granularity (resolution) taught by claims 6.

Applicant also respectfully traverses the implied 35 USC §103(a), rejection of claim 6 based upon failure to meet the 3: "teaching of all claim limitations must be found in the prior art" criteria of MPEP 706.02(j). Nowhere in Soga's claims or specification is there a suggestion that temperature data be obtained with the granularity (resolution) consistent with present claim 6.

Response to section 5, regarding claim 7

This rejection is respectfully traversed in part, and overcome in part. Claim 7 is a dependent claim to claim 1. Amended claim 1, as previously discussed, was not anticipated by Soga.

Applicant also respectfully traverses this rejection on additional grounds. Applicant agrees with examiner that Soga does not clearly disclose the table entry spanning a temperature range of 2 °C or less. As previously discussed, Soga does not, in fact, disclose any fitness for use function of temperature residing with a unitized device of any sort, neither by lookup table or any other means.

Since Soga clearly is not teaching present claim 7 under 35 USC §102(b), and since examiner cites "obviousness" in this rejection, applicant infers that the examiner intended to use a 35 USC §103(a) obviousness rejection rather than a 35 USC §102(b) prior-art objection. Thus applicant will further respond to this rejection assuming that is a 35 USC §103(a) rejection. Here again, the obviousness criteria of MPEP 706.02(j) will be used. Soga fails the suggestion or motivation criteria 1, and the teaching or suggestion of all claim limitations 3.

1: Failure of suggestion or motivation: As previously discussed Soga fails to suggest or motivate a unitized device with a fitness for use function of temperature residing with said unitized device. Claim 7's "function of temperature stored as a lookup table" is a dependent claim to claim 1, which, according to amended claim 1 "resides with said unitized device". No such function of temperature or table was suggested by Soga.

3: Failure to teach or suggest all claim limitations. As previously discussed in the response to the rejection of claim 6, Soga only teaches recording the maximum and minimum and mean temperature during a day. Soga teaches stress and strain equations that don't reside with the unitized device, and which only require temperature extreme data. This is quite different from the "lookup table that has a separate table entry for every temperature throughout the measuring range of the device, and in which each table entry spans a temperature range of 2 °C or less." taught by present claim 7.

Response to section 5, regarding claim 8

This rejection is respectfully traversed in part, and overcome in part. Claim 8 is a dependent claim to claim 1. Amended claim 1, as previously discussed, was not anticipated by Soga.

Note that claim 8 has been amended to replace "display means" with "output signal means" to improve consistency with independent claim 1.

As previously discussed, Soga's "IC with sensor" embedded temperature logger device does not output a fitness for use signal or a fractional remaining stability lifetime of a material. Rather, Soga's "IC with sensor" device outputs the raw time-temperature history, and an "external terminal device" (see Soga Figure 7, item 8, Soga Figure 8 item 84) generates any fitness for use signal.

Applicant thus respectfully traverses this rejection by noting that insofar as Soga's art teaches output of a "fractional remaining stability lifetime" of any sort, Soga's art teaches that fractional remaining stability lifetime would be output by Soga's "external terminal device", rather than on Soga's "IC with sensor" device. This is inconsistent with the "unitized" aspect of the device of claims 1, 11, and 18.

Applicant also respectfully overcomes these rejections by noting that Soga fails to teach other key aspects of the present invention, such as a system in which the function of temperature resides in the unitized device, which amended claims 1, 11, and 18 now incorporate.

Response to section 5, regarding claim 9

This rejection is respectfully traversed in part, and overcome in part. Claim 9 is a dependent claim to claim 1. Amended claim 1, as previously discussed, was not anticipated by Soga.

Applicant further traverses this rejection on the grounds that since Soga's "IC with sensor" device is incapable of generating a fitness-for-use output signal, it should be evident that it would be impossible for Soga's non-existent fitness-for-use output signal to control a temperature logger, which is a key limitation of claim 9.

Response to section 5, regarding claim 10

This rejection is respectfully traversed in part, and overcome in part. Claim 10 is a dependent claim to claim 1. Amended claim 1, as previously discussed, was not anticipated by Soga.

Additionally, applicant respectfully traverses this rejection on the basis that Soga's "IC with sensor" embedded temperature logger device does not generate a fitness for use output signal, and is not suitable for directly controlling a material dispensing device. Rather, Soga's fitness for use output signals are generated by an external terminal device (see Soga Fig. 7 (8)), which in turn may control a material dispensing device.

Response to section 5, regarding claim 11

The rejection of claim 11 is respectfully traversed in part and overcome in part. Claim 11 is essentially a repeat of Claim 1, with the additional limitations that the "*the result of said comparison is used to generate a visual output indicative of the fitness for use of said material*". [emphasis added] and "*the device contains means to allow the function of temperature and reference value to be automatically programmed into an assembled device*".

Thus the previous arguments respectfully overcoming and traversing the 35 USC §102(b) rejection of claim 1 are hereby repeated and incorporated by reference as also supporting overcoming and traversing the 35 USC §102(b) rejection of claim 11.

Applicant also respectfully traverses the 35 USC §102(b) rejection of claim 11 on the basis that Soga does not teach a unitized device with a visual output. This traversal has two aspects. 1: Soga clearly teaches that his visual output resides on his external factory terminal device (see Soga Figure 7, item 8; Figure 8, item 84; and the corresponding descriptions); 2: Soga teaches an "IC with sensor" without any visual output.

Since point 1 is clear, this discussion will focus on point 2 -- that Soga teaches an "IC with sensor" without any visual output. First, note that Soga's "IC with sensor" is mounted on a printed circuit board that is normally inside of an appliance, and thus hidden from view (see Soga Figure 1A, and column 6, lines 42-54). Second, note that Figure 2 of Soga, which discusses the "IC with sensor" in detail, makes no reference to a visual output device. Although Soga Figure 2 does teach a "Transmitter Receiver unit (13)", note that Soga Column 10, lines 33-42 and Column 12, lines 11-14 teaches transmitter receiver unit 13 only in the context of downloading data to Soga's factory terminal device in Soga's disassembly factory, shown in Soga Fig. 7. Further, Soga (Column 10, lines 33-35) discloses that the transmitter unit is a solid-state laser beam, which may not operate in the visible range (infrared solid-state lasers are common for computer data transmission, and Soga, who is apparently unconcerned with visible output, does not state wavelength), and which would not be consistent with safe visual operation.

Additionally, applicant respectfully traverses the 35 USC §102(b) rejection of claim 11 on the basis that Soga's "IC with sensor" does not contain a memory means that store a "predetermined life equation" or stability "function of temperature". As previously discussed, this "predetermined life equation" fitness for use memory means resides on Soga's external terminal device located in Soga's factory. Thus Soga does not teach a unitized device that "contains means to allow the function of temperature and reference value (or "predetermined life equation") to automatically be programmed into an assembled device."

Response to section 5, regarding claim 12

This rejection is respectfully traversed in part, and overcome in part. Claim 12 is a dependent claim to claim 11. Amended claim 11, as previously discussed, was not anticipated by Soga.

Applicant also respectfully traverses this rejection by noting that Soga's Figure 1a and Figure 2, which cover Soga's "IC with sensor" temperature logger, do not contain any memory means allocated to storing the "fitness for use" "predetermined life equation" or "stability" function of temperature, which is the subject for the present claims 10 and 16. Rather, as shown in Soga's Figure 2, the memory means in Soga's "IC with sensor" consists of the program storage memory for controlling Soga's microcomputer time-temperature data logger (18a), and the history data memory for storing Soga's raw temperature and operation history data (18b). As Soga states, Column 10, lines 1-21:

Firstly, the microcomputer control program is written into a memory 18a from an input terminal 27. 18a and 18b consist of a nonvolatile memory such as ROM or EPROM. By the microcomputer 14, the mean temperature T , maximum temperature T_{max} , minimum temperature T_{min} , or temperature difference $\Delta T (=T_{max} - T_{min})$ which is detected from the temperature sensor 15a and the mean humidity, or maximum humidity, or minimum humidity, or humidity change which is detected from the humidity sensor 15b are written and stored in the memory 18b as history data (shown in FIG. 4) of the used condition including the used environment as shown in FIG. 3 in correspondence with the operation time per day, or week, or month and the count of turning ON and OFF which are counted by the timer 15a on the basis of the microcomputer control program which is written into the memory 18a. From a viewpoint of the storage capacity of the memory 18b, the microcomputer 14 converts them to minimum history data of the used condition including the used environment which affects the life of each of the components and joints most and writes them into the memory 18b. [Emphasis added]

Note that Soga's Figures 7 and 8, do not describe the same "IC with sensor" that is shown in Soga's Figures 1 and 2. Rather, Soga Figures 7 and 8 show details of Soga's external terminal device, which downloads data from Soga's "IC with sensor", and subsequently processes the data and computes fitness for use functions.

In contrast to the present invention, Soga's "fitness for use", "predetermined life equation" or "stability" function of temperature resides on an external hard disk.

connected to the external terminal device, which downloads the temperature history data from Soga's "IC with sensor" device. This can be seen in Soga's discussion of the Figure 8, "a concrete constitution of the terminal device" (Column 12, lines 15-16), discussed in detail in Soga Column 12, lines 38-54:

"A numeral 88 indicates an external storage device being constructed of a hard disk and others. The external storage device has stored information including information of whether the components and joints mounted on the printed circuit board body 2a have been reused or not for the past in correspondence with the production number and production date (lot number for some products) being marked on the same printed circuit board body 2a, information of whether the components and joints constituting the electric appliance 1 have been reused or not for the past in correspondence with the production number and production date (lot number for some products) being marked on the same electric appliance 1, and data indicating the relationship between the used condition including the used environment and the guaranteed life being obtained by the severe life test for the components 2a and 3 and joints 7 such as solder." [Emphasis added]

Applicant thus traverses the rejection of claim 12 (and also earlier claim 4) by submitting that Soga is not teaching a unitized device, and that Soga's "fitness for use" predetermined life equation function of temperature exists on a hard disk on a terminal device that is separate from the "IC with sensor" temperature logging device. This function does not reside on a replaceable memory chip on a unitized device, nor is it programmed into a unitized device by any means.

Response to section 5, regarding claim 13

This rejection is respectfully traversed in part, and overcome in part. Claim 13 is a dependent claim to claim 11. Amended claim 11, as previously discussed, was not anticipated by Soga.

As per the response to claim 9, applicant further traverses this rejection on the grounds that since Soga's unitized device is incapable of generating a fitness-for-use output signal, it should be evident that it would be impossible for Soga's non-existent fitness-for-use output signal to control a temperature logger, which is a key limitation of claim 13.

Response to section 5, regarding claim 14

This rejection is respectfully traversed in part, and overcome in part. Claim 14 is a dependent claim to claim 11. Amended claim 11, as previously discussed, was not anticipated by Soga. Soga fails to teach other key aspects of the present invention, such as a system in which the fitness for use function of temperature resides in the unitized device. As previously discussed, independent claims 1, 11, and 18 have been amended to clarify this aspect of the present invention.

As previously discussed for claim 5, applicant further traverses this rejection by noting that in Soga's Figure 4, Soga is clearly teaching "operation time" and "on-off number of time", which clearly teaches against the "continually powered throughout its use lifetime" limitation of claims 5, and 14.

Response to section 5, regarding claim 15

This rejection is respectfully traversed in part, and overcome in part. Claim 15 is a dependent claim to claim 11. Amended claim 11, as previously discussed, was not anticipated by Soga.

Applicant respectfully notes that dependent claim 15 essentially identical to previously discussed claim 6, with the main differences that claim 15 inherits the additional "visual output" and "automatic programmed" limitations of its parent claim 11.

As per previously discussed claim 6, applicant respectfully traverses this rejection on additional grounds. Applicant agrees with the examiner's conclusion that Soga does not

clearly disclose claim 15. In fact, as previously discussed for claim 6, Soga teaches away from claim 15. Soga teaches no fitness for use function of temperature that resides with a unitized device, and only teaches recording daily temperature maximum, minimum, and mean data.

As per claim 6, since Soga clearly is not teaching present claim 15 under 35 USC §102(b), and since examiner cites "obviousness" in this rejection, applicant again assumes that the examiner intended to use a 35 USC §103(a) obviousness rejection rather than a 35 USC §102(b) prior-art objection.

Applicant's arguments traversing the inferred 35 USC §103(a) rejection of claim 15 using the MPEP 706.02(j) criteria are essentially identical to those previously used in the response to section 5, regarding, claim 6 section. To keep this response to a manageable length, applicant respectfully overcomes these claim 15 rejections by use of the same arguments previously used in the "response to section 5, regarding claim 6" portion of this response.

Response to section 5, regarding claim 16

This rejection is respectfully traversed in part, and overcome in part. Claim 16 is a dependent claim to claim 11. Amended claim 11, as previously discussed, was not anticipated by Soga.

Further, as previously discussed for claim 8 (which is similar to claim 16), this rejection is respectfully traversed in part, and overcome in part on additional grounds. As previously discussed, Soga's "IC with sensor" embedded temperature logger device does not output a fitness for use signal or a fractional remaining stability lifetime of a material, and not does not contain display means. Rather, Soga's "IC with sensor" device outputs the raw time-temperature history, and an "external terminal device" (see Soga Figure 7, item 8, Soga Figure 8 item 84) generates any fitness for use signal.

Applicant thus respectfully traverses this rejection by noting that insofar as Soga's art teaches output of a "fractional remaining stability lifetime" of any sort, Soga's art teaches that fractional remaining stability lifetime would be output by the display on Soga's "external terminal device", rather than on Soga's "IC with sensor" device. This is inconsistent with the "unitized" aspect of the device of claims 1, 11, and 18.

Applicant also respectfully overcomes these rejections by noting that Soga fails to teach other key aspects of the present invention, such as a system in which the function of temperature resides in the unitized device. As previously discussed, independent claims 1, 11, and 18 have been amended to clarify this aspect of the present invention.

Response to section 5, regarding claim 17

This rejection is respectfully traversed in part, and overcome in part. As previously discussed, Soga fails to teach other key aspects of the present invention, such as a unitized device, and a system in which the function of temperature resides in the unitized device. As previously discussed, independent claims 1, 11, and 18 have been amended to clarify this aspect of the present invention.

Applicant further respectfully traverses this rejection on the basis that Soga's "IC with sensor" embedded temperature logger device does not generate a fitness for use output signal, and is not suitable for directly controlling a material dispensing device. Rather, Soga's device requires an intermediary external terminal device (see Soga Fig. 7 (8)), which in turn may control a material dispensing device.

Response to section 5, regarding claim 18

This rejection is respectfully traversed in part and overcome in part. As previously discussed in the brief review of Soga et. al, as well as the response to the previous claims, Soga in fact teaches entirely different methods, and fails to teach almost all of the key limitations of present method 18. To reiterate some of these many differences:

1: Soga is not teaching a *"method for monitoring the storage life of materials or for automatically assessing the acceptability of a material's thermal history"*. Rather, he is disclosing a method of monitoring the use life of a circuit board. He does not teach methods suitable for monitoring the thermal degradation characteristics of materials, as his monitoring device is not continually powered, and only records daily temperature maximum and minimum and average values.

2: Soga does not teach a *"unitized time-temperature indicator device"*. Rather, he discloses a non-unitized device in which an "IC with sensor" logger records maximum and minimum and average temperature data for the days in which an internal circuit board is powered on. Soga's data is then relayed to an external terminal device, which interprets this data according to stress and strain functions. This is not unitized, and is not even strictly a time-temperature indicator system because important time-temperature data is not even recorded.

Soga teaches a non-unitized system where at least two distinct devices (the "IC with sensor" and the "terminal device") must interact and share data before a fitness for use determination can be made. This is the exact opposite of "unitized". This teaching of two distinct devices is also apparent in Soga's claim limitations. Note the *"relation being obtained by external reading of the history of temperature"* limitation on Soga's independent claims 1, 4, 5, 6, 7, 8, 9, 10, 11, 12, and 14 [emphasis added]. This limitation is present because Soga's "IC with sensor" device is taking the history of temperature and operational status, and Soga's "terminal device" is reading this history. The remaining Soga independent claim, claim 16, contains the limitation *"system"*, and also the limitation *"a reading unit which reads out at least a history of temperature in correspondence with a history of an operation status from an IC with a sensor"*, which again clearly reads on at least two devices.

Note that nowhere in Soga, including the abstract, column 12 lines 15-65; column 13 line 14 to column 14, line 55, and column 15, lines 1-25, is there any suggestion that it would

be useful for Soga's "IC with sensor" time-temperature logging device to independently calculate fitness for use without the aid of an external terminal device.

Soga was teaching a system by which a recycling factory could decide if a printed circuit board in a product returned for repair or scrap could be recycled or not. Thus Soga teaches the advantages of separating the temperature-logging device from the fitness for use determining device. This is in accordance with other prior art for temperature loggers, and teaches away from the present invention. As Soga states in the "Summary of the invention", column 1, lines 50-65:

An object of the present invention is to eliminate the difficulties mentioned above, and to provide an electric appliance or printed circuit board in which the use history of the electric appliance or printed circuit board on which an LSI and LSI module forming part of the electric appliance are mounted is stored in a memory, and a remaining life of each of electronic components such as the LSI and LSI module can be decided by reading the use history from the memory. Another object of the present invention is to provide a remaining life estimation method and a system thereof which store the use history of an electric appliance or printed circuit board on which an LSI and LSI module forming part of the electric appliance are mounted in a memory, and which decide the remaining life of each of the electronic components by reading the use history from the memory.

[Emphasis added]

For Soga's particular type of application, that of recycling used electronic printed circuit boards, this separation of temperature logging, and fitness for use determining devices, makes perfect sense, and in fact is the preferred way to do things. There is no particular time urgency to recycling printed circuit boards, and typical appliance users would have no great interest in doing so. Thus Soga had no need to burden his embedded "IC with sensor" temperature logger with the added complexity and expense of fitness for use functions. Additionally, since Soga's fitness for use functions reside on an easily accessible factory terminal device, if adjustments to the fitness for use function are

needed after the various appliances have been shipped into the field, these function adjustments would be easy to make.

By contrast, the present invention addresses different applications, such as perishable medical supplies, where user interest in fitness for use is both urgent and high, and evaluation of fitness for use needs to be instantaneous. Here the methods of Soga fail, and the methods of the present disclosure are highly appropriate.

Note however that in contrast to the methods of Soga, the present methods by necessity put the fitness-for-use function into unitized devices that will typically be shipped into the field to various remote locations. After the unitized devices of the present invention have been shipped to the field, corrections or adjustments to the fitness for use functions become very difficult. This trade off is acceptable for situations where the need for instantaneous judgment of fitness for use outweighs the inconvenience and risk associated with an inability to make corrections in such functions, but is very inappropriate for Soga's printed circuit board recycling factory application. Why would Soga choose to burden his appliance manufacturer and recycling factory by embedding hard to change fitness-for-use functions in his printed circuit boards, when it would be much easier and safer just to place general purpose temperature and operation loggers on the circuit boards, and keep the fitness for use functions in an easy to access factory terminal device?

Soga clearly appreciates and makes use of his ability to easily change his "fitness for use" functions in response to additional data. As Soga states in column 14, lines 42-53:

"There is a problem imposed that although there is data by the acceleration test, data of reliability in the actual field is insufficient. According to the present invention, a correspondence between acceleration and an actual environmental load can be established, and the life cycle of a product is made clear, and almost a most suitable reliability design is obtained. The remaining life of each of a product and components constituting the product can be evaluated quantitatively. Therefore, most suitable

decision of minimum energy and cost by remaining life evaluation of each component and energy evaluation (lost energy in the case of disposal of waste) is made possible"

In other words, Soga is adjusting his initial "fitness for use" functions (obtained from accelerated testing), based upon experience obtained from actual field use, to give the best possible "fitness for use" function in his factory terminal device.

Thus Soga contains no suggestion or motivation to produce a unitized device that both collects time-temperature data, and performs "fitness for use" or "stability" calculations based on the data.

3: Soga's device is not *"continually operative throughout the relevant temperature monitoring range of the device"*. Rather, Soga's device only records daily temperature minimum, maximum, and mean data. Intermediate temperature data is not recorded, and thus this device is not continually operative within the present specification's meaning of the term.

4: Soga's "IC with sensor" device does not contain any way to *"assess the acceptability of a material's thermal history"*. No memory is allocated to this non-existent (for Soga) function, and no way to program this non-existent (for Soga) function is shown.

5: Soga's "IC with sensor" device does not have an equivalent fitness for use *"function of temperature"*, and does not perform an equivalent sum.

6: As previously discussed, Soga does not teach methods in which *"the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate impact of time and temperature on the detectable property of the material"*. Soga teaches only daily minimum and maximum recording, which has a very large granularity that is inadequate for the objectives of the present disclosure.

As previously discussed, note that in Soga's Figure 4, which teaches the "history data of the printed circuit board"; Soga's embedded "IC with sensor" device only stores the temperature maximum, minimum, and mean for the day. No other intermediate temperature values are stored. This teaching of an "IC with sensor" that only records temperature maximum, minimum, and mean for the day is also found in the Soga's specification (Soga Column 2, lines 30-40; Column 2 lines 60-65; and Column 10, lines 5-21).

As previously discussed, note that Soga does not record time and temperature data with more resolution (granularity) because Soga's "predetermined life equation" is quite different from the "function of temperature" taught in the present disclosure. Soga's specification (column 7, lines 20 to column 9, line 31) teaches solder joint life calculation formulas 1 and 2 (Soga column 7, lines 25-58), based on the Coffin Manson Equation for mechanical Fatigue. Mechanical fatigue is responsive to temperature extremes, and Soga's formulas 1 and 2, require only a maximum and minimum temperature in order to calculate a ΔT and T_{max} value. As a result, Soga did not feel the need to teach obtaining and processing small granularity temperature values.

7: Soga's "IC with logger" does not output a *"fitness for use"* output signal.

As previously discussed, Soga does not teach a unitized device with a function of temperature resides with said unitized device that also contains "an output signal indicative of the fitness for use". Rather, as previously discussed, Soga's *fitness for use* output resides on his external terminal (Soga Figure 8, item 84).

Again, Soga's failure to suggest, motivate, or teach a unitized storage life monitoring method with "an output signal indicative of the fitness for use" is understandable in the context of Soga's applications. Soga was teaching an embedded temperature logger that was placed in an internal printed circuit board of an appliance. The user would have no way of making meaningful sense of the raw logger data, which did not contain any fitness for use assessment.

Response to section 5, regarding claim 20

This rejection is respectfully traversed in part, and overcome in part. Claim 20 is a dependent claim to claim 18. Amended claim 18, as previously discussed, was not anticipated by Soga.

Applicant further respectfully traverses this rejection on the grounds that since Soga teaches a non-unitized system that requires a factory terminal device in order to render a fitness for use output signal, Soga's device in fact does not remain associated with the material throughout the majority of the material's storage life.

35 USC §103(a) rejections**Response to section 7, regarding claim 19**

Applicant respectfully traverses this 35 USC §103(a) rejection on the basis that it fails MPEP 706.02(j) (previously discussed) on multiple grounds.

The many differences between Soga and the present art were discussed elsewhere in this response. The aspect of Nicholson's teaching that concerns resistance-capacitance methods of measuring thermistor values was previously known in the art and was disclosed by other sources including Texas Instruments (MSP430 family Software Users Guide, 1994, p 9-18 to 9-21; MSP430 Family, Metering Application Report, 1997, p 42-45)). This part of Nicholson's teaching adds nothing to the art of Soga since Soga's teaching is not limited to any specific electronic method of interrogating the temperature status of a thermistor, and in fact Soga was probably using this type of method.

Although Nicholson also teaches temperature alarm (thermal alarm) methods, at most combining Soga's "IC with sensor" with Nicholson's temperature alarms would give Soga's "IC with sensor" the additional ability to now indicate by a visual display if Soga's circuit board had reached an acceptable temperature range within an acceptable time

period, or whether the temperature of Soga's circuit board had an upward trend prior to reaching the acceptable range, or whether Soga's circuit board had been exposed to temperatures outside of a pre-set temperature.

However no combination of Soga or Nicholson teaches or motivates the important claim limitations of present independent claim 18, which forms the basis of dependent claims 19 and 21. A combination of Soga and Nicholson fails to meet the standards of a 35 USC §103(a) obviousness rejection under the MPEP 706.02(j) criteria on many grounds.

To keep this response to a manageable length, only a few of the many failures under the MPEP 706.02(j) criteria will be discussed here.

1: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest, or motivate the present claim 18 limitation of: *"A method for monitoring the storage life of materials."* Soga teaches a method for monitoring the operation status of a circuit board. Nicholson teaches shipment and temperature trend monitors, but his methods are incapable of monitoring the storage life of materials, as claimed by present claim 18.

2: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest, or motivate the present claim 18 limitation of: *"modeling the thermal degradation characteristics of the material as a function of temperature and time based upon a plurality of experimental data points"*. This is, of course, required in order to monitor the storage life of materials.

3: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest or motivate the present claim 18 limitation of: *"using the time-temperature parameters from this model to program a unitized electronic time-temperature indicator device to automatically assess the acceptability of a material's thermal history."* [emphasis added] As previously discussed, neither Soga nor Nicholson teach a device that is programmable in this regard.

4: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest or motivate the present claim 18 limitation of a device that: *"periodically samples the temperature and computes*

a function of temperature that is continually operative throughout the relevant temperature monitoring range of the device". Neither Soga nor Nicholson are continually operative. Soga's "IC chip with sensor" simply records daily maximum, minimum, and mean temperatures. Nicholson's device simply triggers on one or more preset temperature ranges, and ignores temperature ranges outside of the preset ranges.

5: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest or motivate the present claim 18 limitation of a unitized device that: *"wherein said function of temperature approximates the impact that the relevant temperature, for that period's length of time, has on a detectable property of said material; and wherein said computational means generate a running sum of said function of temperature over time"* Soga's failure to teach this was previously discussed at length. Note that Nicholson fails to teach such functions of temperature and fails to teach generating running sums of such (non-existent to Nicholson) functions of temperature over time.

6: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest or motivate the present claim 18 (as amended) limitation of a unitized device that: *"and wherein said function of temperature resides with said unitized device;"* Soga teaches a non-unitized logger and factory terminal analysis system. Nicholson fails to teach such functions of temperature.

7: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest or motivate the present claim 18 (as amended) limitation of a device that: *"and wherein the granularity of the function of temperature is small enough, and the frequency of time measurements is often enough, as to substantially approximate the impact of time and temperature on the detectable property of said material;"* As previously discussed in the failure to meet the "function of temperature that is continually operative" discussion in (4) above, Soga simply teaches recording maximum and minimum and average temperatures on a daily basis, which does not have an adequate small granularity and frequency for monitoring the storage life of materials.

Although Nicholson does disclose monitoring the temperature of blood and pharmaceuticals, he does so primarily in the context of monitoring the "shipping" of these products. This is because during shipment and routine storage, these materials are normally subjected to a very limited range of temperatures, for example 2 to 8 °C. Nicholson essentially teaches a prior art "thermal alarm," previously discussed in the prior art section of the present specification (paragraph 26-32). These thermal alarm methods are incapable of realistically dealing with real-world storage conditions outside of limited duration shipping situations, and storage in well controlled refrigeration units.

Outside of shipping and well-controlled temperature storage, Nicholson's temperature alarm methods have the same weakness as other prior art temperature alarm methods. These methods are generally inadequate for monitoring the storage life of the materials of claim 19, "food, chemicals, biotherapeutics, vaccines, drugs, medical diagnostics, blood, blood products, cut flowers, and post harvest agricultural materials", many of which may have a storage life far less than a day in some situations, and many of which have sharp temperature cutoffs where the storage lifetime abruptly becomes zero above or below certain specific temperatures. Note also that Nicholson fails to teach "*substantially approximate the impact of time and temperature on the detectable property of said material;*" At most, Nicholson's device could be set to monitor the temperature cutoff at which the storage lifetime would abruptly become zero, but Nicholson's device is incapable of "*approximating the impact of time and temperature on the detectable property of said material*" at other temperatures. Nicholson's device is not "continuously operative" (see present response, pages 17-18).

8: Neither Soga, Nicholson, or Soga + Nicholson teach, suggest or motivate the present claim 18 (as amended) limitation of a device that: "*which said running sum is compared to a reference value, and the result of said comparison is used to generate an output signal indicative of the fitness for use of said material.*" Neither Soga nor Nicholson generate such running sums or compare such sums to this type of reference value. Soga teaches a non-unitized IC with sensor and factory terminal analysis system, and does not teach a unitized device that "*outputs a signal indicative of the fitness for use of said*

material." Nicholson fails to teach the generation of equivalent running sums and comparing such running sums to a reference value equivalent to that of present claim 18.

Response to section 7, regarding claim 21

Please note that applicant has amended 21 to now be a dependent claim to claim 18 rather than claim 19. The original claim 19 dependence was an untended typographical error in the original application. Applicant believes that this change otherwise has no material effect on this response.

As per the response to section 7, regarding claim 19, applicant respectfully traverses this 35 USC §103(a) rejection on the basis that it fails the previously discussed MPEP 706.02(j) tests (previously discussed) on multiple grounds.

To keep this response to a manageable length, applicant notes that claim 21 simply teaches a specific way to implement claim 18's function of temperature, and claim 19 simply teaches some specific applications for the method of claim 18. Thus the MPEP 706.02(j) traversal of the rejection of claim 21 is essentially identical with the MPEP 706.02(j) traversal of claim 19 discussed in the previous section (response to section 7, regarding claim 19). To keep this reply to a manageable length, this claim 19 traversal is repeated and incorporated herein for claim 21 by reference.

Double Patenting rejections

Response to section 8:

Claims 1, 3-6, 8 and 10 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6 and 8 of parent application 10/634,297 (now US patent 6,950,028).

Applicant respectfully traverses this rejection on the first grounds that according to MPEP 804, the parent patent (in this case US patent 6,950,028) is owned by the applicant, cannot be used as prior art in an obviousness-type double patenting rejection. According to MPEP 804:

A double patenting rejection of the obvious-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. In re Braithwaite, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obvious-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. In re Braat, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Since the analysis employed in an obvious-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claim and the prior art relative to a claim in the application at issue;*
- (B) Determine the differences between the scope and content of the patent claim and the prior art as determined in (A) and the claim in the application at issue;*
- (C) Determine the level of ordinary skill in the pertinent art; and*
- (D) Evaluate any objective indicia of nonobviousness.*

The conclusion of obvious-type double patenting is made in light of these factual determinations.

Any obvious-type double patenting rejection should make clear:

(A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and

(B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent.

When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. [emphasis added]

Applicant respectfully traverses this rejection on the grounds that, according to MPEP 804, the disclosure of the parent application of the present disclosure, patent 6,950,028, which is both invented by and owned by the inventor of the present disclosure cannot be used as prior art in an obviousness-type double patenting rejection for this application. Since no additional prior art was cited in section 8, applicant must respectfully conclude that with the exclusion of 6,950,028 as prior art, and nothing else cited, no basis for an obviousness-type double patenting rejection must exist here.

Here, applicant assumes that examiner may have intended a statutory double patenting rejection. In order to expedite prosecution, applicant will assume that this is the case, and also give a statutory double patenting response.

Applicant further respectfully traverses examiners assertion that present claims 1, 3-6, 8 and 10 contain all the limitations of claims 1, 3, 4, 5, 6, and 8 of US patent 6,950,028. Rather, applicant respectfully submits that these present claims lack the "external material" limitation of the parent 6,950,028 application, and are therefore broader.

Applicant submits that the broader present claims satisfy the statutory criteria that there is an embodiment of the invention that falls within the scope of the new claims that does not fall within the scope of the old claims.

The MPEP criteria used to test for the presence or absence of statutory double patenting is shown below:

804 Definition of Double Patenting [R-3] II. REQUIREMENTS OF A DOUBLE PATENTING REJECTION (INCLUDING PROVISIONAL REJECTIONS) A. Statutory Double Patenting - 35 U.S.C. 101

*In determining whether a statutory basis for a double patenting rejection exists, the question to be asked is: Is the same invention being claimed twice? 35 U.S.C. 101 prevents two patents from issuing on the same invention. "Same invention" means identical subject matter. *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1984); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).*

*A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist. For example, the invention defined by a claim reciting a compound having a "halogen" substituent is not identical to or substantively the same as a claim reciting the same compound except having a "chlorine" substituent in place of the halogen because "halogen" is broader than "chlorine."* [emphasis added]

Applicant respectfully traverses a potential statutory double patenting rejection on the grounds that the prior '028 patent claims all contain an "external" material limitation. That is, time-temperature monitors constructed using a circuit board containing a material that altered its fitness for use properties as a function of its time-temperature thermal history would not be covered under the '028 claims. By contrast, the present claims do not contain this "external" limitation. Thus time-temperature monitors that monitor a

circuit board containing a material that altered its fitness for use properties as a function of its time-temperature thermal history would be covered under the present claims.

Although now broader, the present claims still are quite different from the claims of Soga et. al. As an example, a device operating under the present claims would be able to directly output a fitness for use output signal without having to be processed by a factory terminal device (as is the case with Soga). A device operating under the present claims can operate continuously, rather than only when an appliance is operating, as is the case with Soga. A device operating under the present claims can adequately cope with monitoring the real-world stability of complex biological materials, rather than simply monitoring stress and strain of electronic circuit boards, as is the case with Soga. As should be evident by now from the discussion of the claims, many other differences also exist.

This type of device would also be quite different from the prior art device of Sjöholm et. al. (WO01243472A1). Although Sjöholm's device is a time-temperature monitoring device that contains a conductive time-temperature-sensitive enzyme-substrate component as an essential part of the devices' circuit, Sjöholm's device differs in many other ways from the present disclosure. Sjöholm teaches away from devices containing the computational means of the present disclosure, and does not teach functions of temperature, running sums, or many other limitations of the present disclosure. Rather, Sjöholm teaches away from this art, and teaches an electric circuit without computing means that is activated by an electric field or magnetic field and generates a signal that depends upon the electrical resistance of the time-temperature-sensitive enzyme-substrate component.

The main goal of any double patenting rejection is to prevent the unjustified or improper timewise extension of the "right to exclude". Applicant respectfully overcomes any further double patenting rejections by stating that applicant is common owner of the cited 6,950,028 patent and the present disclosure. Applicant agrees to make allowance of these claims contingent upon applicant's signing a terminal disclaimer.

Response to section 9:

Claims 2, 7, 9, 11-18, and 20 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable in view of claims 1 and 9-15 of parent application 10/634,297 (US patent 6,950,028) and in view of Soga.

As previously stated in the response to section 8, MPEP 804 rules state that when considering a parent patent versus a continuation application in a obviousness-type double patenting rejection: the disclosure of the patent may not be used as prior art [emphasis added]

Thus applicant respectfully traverses these rejections on the grounds that under MPEP 804, the disclosures of parent patent 6,950,028, invented by and presently owned by the applicant, should not be cited against the present application. Absent the teaching of parent patent 6,950,028, applicant respectfully submits that the art of Soga, cited by the examiner, stands alone and thus fails the subsequent 35 U.S.C. 103(a) obviousness test under multiple grounds.

The many differences between Soga and the present art were discussed elsewhere in this response. To keep this response to a manageable length, only a few key differences will be repeated here.

- 1: Soga fails to disclose a function of temperature, whether multi-element look up table or other function, that resides with said unitized device, as is taught by all present claims.
2. Soga fails to disclose means to allow a function of temperature and a reference value to be automatically programmed into a unitized device wherein wherein said function of temperature resides with said unitized device.

3: As previously discussed, Soga's "IC with sensor" temperature logger can not calculate fitness for use, and thus can not generate a fitness for use output signal necessary to control a logger, as taught by present claim 9.

Applicant also respectfully traverses any potential statutory double patenting rejection on the grounds that present independent claims 1, 11, and 18 lack the "external material" limitation of corresponding independent claims in US patent 6,950,028, and are thus broader than the corresponding independent claims in US patent 6,950,028. As per the response to section 9, and discussed in more detail in the section 9 response, it is possible to construct embodiments of the invention that fall within the scope of the present claims that do not fall within the scope of the previous claims.

Here, time-temperature monitors comprised of a circuit board containing a perishable component would be covered under the present claims 2, 7, 9, 12-17 and 20, but would not have been covered under claims 1 and 9-15 of parent application US patent 6,950,028.

The main goal of any double patenting rejection is to prevent the unjustified or improper timewise extension of the "right to exclude". Applicant respectfully overcomes any further double patenting rejections by stating that applicant is common owner of the cited 6,950,028 patent and the present disclosure. Applicant agrees to make allowance of these claims contingent upon applicant's signing a terminal disclaimer.

Response to section 10:

Claims 19 and 21 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable in view of claims 15 of parent application 10/634,297 (US patent 6,950,028) and in view of Soga and Nicholson.

As previously stated in the response to section 8, MPEP 804 rules state that when considering a parent patent versus a continuation application in a obviousness-type double patenting rejection: the disclosure of the patent may not be used as prior art [emphasis added]

Thus applicant respectfully traverses these obviousness-type double patenting rejections on the grounds that under MPEP 804, the disclosures of parent patent 6,950,028 should not be cited against the present application. Absent the teaching of parent patent 6,950,028, applicant respectfully submits that the art of Soga and Nicholson (patent 6,320,512), cited by the examiner, thus standing alone, fails the subsequent obviousness test under 35 U.S.C. 103(a) under the same multiple grounds previously used in the previous 35 U.S.C. 103(a) response to section 7, regarding claim 19, and response to section 7, regarding claim 21.

As previously discussed in response to section 7, regarding claim 19, and response to section 7, regarding claim 21, applicant respectfully traverses the obviousness-type double patenting rejections of claim 19 and 21 on the basis of the failure of any combination of Soga and Nicholson to satisfy a large number MPEP 706.02(j) tests for 35 USC §103(a) obviousness criteria for independent claim 18, which forms the basis for dependent claims 19 and 21.

The main goal of any double patenting rejection is to prevent the unjustified or improper timewise extension of the "right to exclude". Applicant respectfully overcomes any further double patenting rejections by stating that applicant is common owner of the cited 6,950,028 patent and the present disclosure. Applicant agrees to make allowance of these claims contingent upon applicant's signing a terminal disclaimer.

Response to section 11:

As previously discussed, Applicant is the common owner of the cited 6,950,028 patent and the present disclosure. Applicant is willing make allowance of all claims of the

present invention contingent on filing a terminal disclaimer. Applicant respectfully requests that examiner assume that the offer to sign such a terminal disclaimer forms part of applicant's present response to the rejections of present claims 1-21, as well as new claims 22-24.

Amended claims;

Claim 19 had been amended to further include vaccines. Vaccines were included in the prior art discussion in specification paragraph 15:

"There are several different brands of visual Arrhenius-type time-temperature indicators in current use. For example, TempTime Corporation, Morris Plains, New Jersey, produces the Heatmarker® Time-temperature indicator for medical use. This indicator, often used to insure the integrity of vaccines in third-world countries, relies upon the progressive darkening of a chemical indicator, normally placed in the center of a "bull's eye" visual colorimetric reference pattern." [emphasis added]

Applicant respectfully submits that the present time-temperature indicator, being an improvement on prior-art time-temperature indicators, is clearly suitable for all applications that prior-art time-temperature indicators were used for. That the present invention can handle Arrhenius type time-temperature uses was discussed in the specification paragraphs 41 (which discloses that the invention can do both Arrhenius type time-temperature profiles and more advanced non-Arrhenius time-temperature profiles), paragraphs 127 and 130 (which shows an Arrhenius type equation), and paragraphs 169 and 170.

As previously discussed, amended claim 21 is now a dependent claim of claim 18.

New claims:

New claims 22-24 contain additional limitations that specify how a temperature logger, controlled by the fitness for use output signal of the basic invention, may operate. These claims are essentially further extensions of fitness-for-use controlled temperature logger claim 9, and teach more details of how such a fitness-for-use controlled temperature logger may operate. These additional limitations find support in specification paragraphs 93 to 96, paragraphs 164-166, and figure 8.

New independent claim 24, which also teaches a further radiofrequency output limitation, finds support for this additional limitation in prior claim 3 and specification paragraphs 55, 86, and 117.

New dependent claim 25 finds support in specification paragraph 118.

Replacement drawing sheets:

The replacement drawing sheets for objected to drawings 2 and 7 follow. As previously stated, these corrections add no new material because the "blank boxes" in the original drawings 2 and 7 were labeled with numbers, and the meaning of the numbers defined in the specification. The changes here simply bring the same labeling forward onto the drawings, making reading more convenient.

Note however, that label (8) indicating the "Test button" was inadvertently omitted from original drawing 2. This has been corrected here by adding label (8). This label was present in the analogous drawing 1 from prior art patent 6,950,028 as label (7) "Test button". Since test button (8) was also discussed in the present specification paragraph 57, correcting this omission adds no new material to the specification.

Since the issue of Soga has been raised, applicant believes that it would expedite prosecution to further discuss how differences between the present specification's

drawings 2 and 7, and the drawings of Soga et. al. (in particular Soga Figures 2, 7, and 8) may be used to clarify the differences between the present art, and the prior art of Soga et. al.

Differences between the present invention and the art of Soga et. al. can clearly be seen by comparing Figure 1 of the present invention with Figure 2 of Soga. Note that Soga's "IC with sensor" device, which functions as an embedded microcomputer or microprocessor controlled temperature logger, shows a data flow arrow starting at Soga's "Microcomputer" (14) and ending at Soga's "History Data" (18b). By contrast, Figure 2 of the present invention shows a different configuration, in which the data flow arrow starts at "Stability Memory" (3) and ends at "Microprocessor" (1).

The "History Data" (18b) memory of Soga's Figure 2, stores a record of the temperatures and operating conditions observed by Soga's "Temperature Sensor" (15a). Soga's "History Data" memory does not store any fitness for use parameters. Soga's fitness for use parameters are stored in Soga's external terminal device, shown in Soga's Figure 7 item 8, and in Soga's Fig. 8 as the "External Storage Device" item 88. Also see Soga column 12, lines 38-54.

By contrast, the "Stability Memory" (3) shown in Figure 2 of the present invention contains stability parameters, used by the device to internally calculate fitness for use. Applicant respectfully submits that this "Stability Memory (3)" (Fig. 2 present disclosure) does not correspond to Soga's "History Data" (18b) (Fig. 2 Soga). Rather, "Stability Memory" (3) more closely corresponds to the *"data indicating the relationship between the used condition including the used environment and the guaranteed life being obtained by the sever life test for the components 2a and 3 and joints 7 such as solder"* (Soga Column 12, lines 50-54) that is stored in Soga's "External Storage Device" attached to Soga's external terminal (Soga Fig. 8, (88)).

Differences between the present invention, and the art of Soga, can be also clearly seen by comparing Figure 7 of the present invention with Figure 7 of Soga. In Figure 7 of the

present invention, the arrow, showing the direction of data flow on programming cable (2), starts from the personal computer (1) and ends at the Programmable Electronic Time-Temperature Indicator (3), and the cable (2) itself is described as a "programming cable". As the specification for the present invention states:

Programming the device: After the "F" and P(temp) data have been calculated, the "F" value and table of P(temp) values are downloaded electronically into the device through the unit's data input jack, or manually through memory chip placement. The programmed device is then ready to use.

To do this, the table of P(temp) values is entered into a data download program, which may run on a personal computer (PC), or other programming system. The device is then connected to the PC's data transfer port via an adapter cable, and the data transferred. After the data is downloaded, the program and microprocessor on the device itself may automatically check the success of the download by comparing the data to a checksum. A schematic of this download process is shown in Figure 7. Here, a programming device, such as a personal computer (1) transmits data over a programming cable (2) to a programmable electronic time-temperature indicator (3). (Present specification, paragraphs 119 and 20)

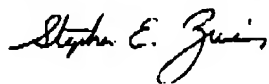
By contrast, Figure 7 of Soga shows Soga's temperature history data flowing from Soga's History Data memory (Soga Figure 2, item 18b), located on Soga's "IC with sensor" (Soga Fig. 7, item 4) to Soga's external terminal (Soga Figure 7, item 8) by way of a cable (Soga Figure 7, item 73) that is used for "inputting data" (Soga Column 12, line 60) to Soga's external terminal. Although the correspondence between the numbers in Soga's Figure 7, and Soga's specification itself, is in certain sections difficult to follow, the general pattern is clear. Soga's raw temperature history data is an entirely different type from the present specification's fitness for use function data (temperature history rather than stability parameters used to compute fitness for use), and Soga's data flows in a different direction (from the device containing the temperature sensor to an external

terminal, rather than from a device that generates fitness for use data to the device containing the temperature sensor).

In view of the above amendments, corrected figures, and accompanying remarks, applicant believes that the application is now in condition for allowance. Notice to that effect is respectfully requested.

If the examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at (408) 348-1495.

Respectfully Submitted

A handwritten signature in cursive script, reading "Stephen E. Zweig".

Stephen E. Zweig, Ph.D.

Inventor